0327-0815-0

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

#25
4-23-03

IN RE APPLICATION OF :

Keiko HASEBE, et al. : EXAMINER: WELLS

SERIAL NO.: 09/468,777 : GROUP ART UNIT: 1617

FILED: DECEMBER 21, 1999 :
CPA Filed: November 20, 2001

FOR: AMPHIPATIC LIPID :
DISPERSION

REPLY BRIEF

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

The following is a reply to the examiner's answer of February 12, 2003, in response to appellants' appeal of November 18, 2002.

Item 2

The examiner's answer states that the brief does not contain a statement identifying the related appeals and interferences and therefore it is presumed that there are none.

The examiner is in error.

Appellants have already stated, in item 2 of their appeal brief that

> "Appellants, Appellants' legal representative and the Assignee are **not aware** of any related appeals and interferences which will directly affect or be directly affected, or have a bearing on the Board's decision in the pending appeal".(emphasis added)

The rules only require identification of other appeals or interferences **known** to appellant, the appellant's legal representative or assignee. Appellants' statement that they are

not aware of any related appeals can not be more clear. As such, appellants' appeal brief of November 18, 2002 is believed to be in compliance with 37 C.F.R.(c)(2).

Item 10

The present invention is directed to a dispersion of an amphipathic lipid as a solid particulate dispersed in a surfactant and aqueous medium (page 3, lines 5-23 of the specification). As a dispersion, the amphipathic lipid is present as solid particles, surrounded by a liquid phase of surfactant and aqueous medium. The claim limitations of 1) the amphipathic lipid being present as a solid particulate; 2) the solid particulate being dispersed in the surfactant and aqueous medium; and 3) the solid particulate having a particle size from from 0.5 to 150 μm are claim limitations which are simply not found in the cited reference. As such the examiner has committed reversible error in concluding the claims to be obvious in the absence of a teaching of these claim limitations.

The References Fail to Describe the Amphipathic Lipid being Present as a Solid Particulate

In the examiner's answer, the examiner erroneously concludes that the amphipathic lipid in the composition of *Nakamura* is present as a solid particulate (page 7, line 5 of Examiner's Answer). The examiner reaches this conclusion based on the disclosure in *Nakamura* that 1) the amphipathic lipid is microdispersed in the cosmetic composition; 2) the lipid is a solid at room temperature; and 3) the composition is transparent or semi-transparent (page 7, lines 1-5 of Examiner's Answer).

The examiner's conclusion is in error for at least the reasons as follows:

Nakamura et al. describe a cosmetic composition in which the amphipathic lipid is present as a liquid dispersoid. The composition is prepared by melt mixing the amphipathic lipid (A), nonionic surfactant (B) and/or ionic surfactant (C). While the lipid **prior to** melt mixing with the surfactant, is a **solid** at room temperature (page 2, lines 48-49 of *Nakamura*),

after melt mixing the amphipathic lipid with the surfactants, the lipid no longer exists as a solid, but is transformed into an anisotropic liquid crystal phase of amphipathic lipid and surfactant. The mixture of lipid and surfactant exists within the final composition as a lipid microdispersion (page 4, lines 19-20 of *Nakamura et al.*). The lipid is not present as a solid particulate, but rather as a microdispersion of an anisotropic liquid phase of lipid and surfactant The reference describes a microdispersion of lipid and surfactant in an aqueous medium, not a lipid as a solid particulate in a surfactant and aqueous medium. Accordingly, the examiner has committed clear and reversible error in concluding that *Nakamura* discloses a composition in which the lipid is present as a solid particulate dispersed in surfactant and an aqueous medium.

It is clear that the lipid of *Nakamura* is not present in the form of a solid particulate as the reference already describes that the lipid undergoes a change in physical properties. The lipid itself is a solid at room temperature, however after blending with the surfactant, is converted into an anisotropic liquid crystal phase. The change in phase from a solid to an anisotropic liquid crystal is evidence that the lipid is not present as a solid particulate.

Dubief et al. simply describes a composition considered to be an emulsion. The reference describes formulation of the composition by forming a paste of the cationic surfactant and ceramide, followed by melting the mixture at a temperature of about 80 °C (column 3, lines 38-43 of *Dubief et al.*). Thereafter hot water is added, with vigorous stirring using an Ultraturrax. The result is the production of an emulsion.

Dubief et al. describes a composition prepared by melting the surfactant and lipid, then adding water. The result is an emulsion of **ceramide (lipid) and surfactant** in water. As a mixture with surfactant as an anisotropic liquid crystal phase, the lipid is not present as a

solid particulate. There is no disclosure of the lipid being present as a solid particulate, as claimed.

Pillai et al. does not disclose any solid particles of lipid whatsoever. Since the reference fails to disclose or suggest solid particles of amphipathic lipid in any context, the reference can not suggest a dispersion in which the amphipathic lipid is a **solid particulate** dispersed in a surfactant and aqueous medium. As the reference fails to describe a composition in which the amphipathic lipid is in solid form, the reference can not suggest an amphipathic lipid as a solid particulate which is dispersed in surfactant and aqueous medium. Accordingly the claim limitation of the amphipathic lipid being a **solid particulate** is a claim limitation which is not found in the cited reference and accordingly the claimed invention can not be found to be obvious therefrom.

The examiner has cited the secondary references of *Vanlerberghe et al.* and *Young* as teaching compositions in which the particle size overlapped the claimed range of 0.5 to 150 μm and that it would have been obvious to have formulated the compositions of *Nakamura et al.* and *Dubief et al.* to have a particle size of lipid, as a solid particulate,within that claimed as the secondary references are also directed to compositions comprising wax, surfactant and an aqueous medium and all three references related to cosmetic compositions. The examiner further argues that the rejection is based on the combination of references and not the references individually.

In spite of the teachings of the secondary references that a microdispersion may have a particle size as claimed, such a teaching does not suggest changing the anisotropic liquid crystal phase dispersion of lipid and surfactant of *Nakamura* and *Dubief et al.* into a solid particulate of lipid, as claimed.

There is no motivation provided by the secondary references to formulate the compositions of *Nakamura et al.* and *Dubief et al.* to have the amphipathic lipid present as a solid particulate, as *Nakamura et al.* and *Dubief et al.* teach that the **lipid and surfactant** are to be melted together to form a new liquid crystal phase. Evidence that the amphipathic lipid is not present as a solid particulate is found in the report by *Nakamura et al.* of the phase change of the amphipathic lipid from being a solid, to existing, in conjunction with the surfactant, as an anisotropic liquid crystal phase.

In contrast, the present invention is directed to a dispersion of amphipathic lipid as a solid particulate. The claim limitation of the amphipathic lipid being a solid particulate is a claim limitation which is not found in the cited references. Quite to the contrary the primary references, at best teach formulation of the amphipathic lipid as an anisotropic liquid crystal phase of lipid with the surfactant.

The examiner simply has taken the references for their teachings of the elements of an amphipathic lipid, a surfactant and water as well as the use of the term microdispersion and concluded, that it would be obvious to provide a composition in which the lipid is present in the form of a solid particulate. Such a conclusion is simply not supported by the record. More specifically, the cited references teach that the lipid is present in a very specific state, being an anisotropic liquid crystal phase with the surfactant, which does not suggest providing the lipid as a solid particulate.

Accordingly, the decision of the primary examiner must be reversed.

The References Fail to Describe the Amphipathic Lipid being Dispersed in the Surfactant and Aqueous Medium

The primary references fail to disclose or suggest that the solid particulate of lipid is dispersed in the surfactant and aqueous medium.

According to *Nakamura* and *Dubief et al.* the amphipathic lipid and the surfactant are melt mixed, and then aqueous phase is added (page 4, lines 19-20 of *Nakamura* and column 3, lines 38-43 of *Dubief et al.*) As described by *Nakamura* such a process transforms the **lipid and surfactant** into a new anisotropic liquid crystal phase of lipid and surfactant. The references describe a dispersion of **lipid and surfactant** in the aqueous phase and not a dispersion of the lipid in the surfactant and aqueous phase. As the primary references disclose that the lipid forms a new liquid crystal phase with the surfactant, it is not possible for the lipid to be dispersed in the surfactant and aqueous medium.

As to *Pillai et al.*, nowhere in this reference is there a disclosure that **the lipid** is dispersed in the surfactant and aqueous phase. The reference describes the possible inclusion of surfactants, also designated as emulsifiers (column 13, lines 45-47 of *Pillai, et al.*) and that such composition would be present as a water-in-oil emulsion or as an oil-in-water emulsion, depending on the HLB of the emulsifier (column 12, lines 26-30 of *Pillai, et al.*). As such, the reference clearly does not suggest that the amphipathic lipid is present as a solid particulate dispersed in surfactant and aqueous medium, but rather teaches, that when a surfactant is present the composition takes the form of an emulsion, not a dispersion.

The References fail to Describe the Solid Particulate having a Particle Size of from 0.5 to 150 μm

Nowhere do the cited references suggest that the amphipathic lipid is a solid particulate having a particle size of from 0.5 to 150 μm.

As previously discussed, *Nakamura* and *Dubief et al.* fail to describe the state of the amphipathic lipid as a solid particulate. Therefor, the reference can not possible describe that the amphipathic lipid is a solid particulate having a particle size of from 0.5 to 150 μm. While *Nakamura* uses the term "microdispersion", the reference can not possibly be referring to a microdispersion of the amphipathic lipid as a solid particulate as the references describe the amphipathic lipid as being in an anisotropic liquid crystal phase.

Neither the Method as Claimed Nor the Product of Such Method Are Suggested by the Cited References

Claims 16 and 20 directed to a dispersion and a process of preparing a dispersion in which lipid, surfactant and aqueous medium are heated to not less than the melting point of the lipid are not suggested by the cited references.

As discussed above, *Nakamura et al.* and *Dubief et al.* describe a process in which lipid and surfactant are melted together, **then** aqueous medium is added (page 4, lines 18-20 of *Nakamura* and columne 3, lines 38-43 of *Dubief et al.*) The aqueous medium is not added until after the lipid and surfactant have been melted together.

In contrast, the claimed process is directed to a method of preparing a dispersion in which lipid, surfactant and aqueous medium are heated to not less than the melting point of the lipid. Thus the two methods are fundamentally different, in that the reference does not include water during the melting of lipid and surfactant, while in the present method, lipid, surfactant **and water** are heated together.

As discussed above, *Pillai et al* fails to disclose or suggest a particle size for the lipid component in any fashion. The reference fails to suggest melting the lipid, surfactant and water together. The claim limitation of the heating of the lipid, surfactant and aqueous

medium, together to a temperature of not less than the melting point of the lipid is a claim limitation which is not found in the cited references and accordingly the claims are not obvious.

For the first time, in the examiner's answer, the examiner relies **not** on the method described by *Nakamura* for the obviousness of the claimed method, but rather notes that the secondary reference of *Vanlerberghe et al.* describes a process in which wax and emulsifier are heated, optionally with oils and lipsoluble substances, at a temperature greater than the melting temp of the mixture but not greater than 100°C, optionally in the presence of water, forming a microemulsion the cooling to form a microdispersion. Quite simply there is no motivation to use the method of *Vanlerberghe et* al. to prepare the dispersion of *Nakamura* as *Nakamura* provides a specific method of making the described microdispersion, in the absence of the aqueous phase. The two processes are inconsistent in that one heats in the absence of the aqueous phase, while the other heats in the optional presence of the aqueous phase. As *Vanlerberghe et al.* does not describe the preparation of a composition containing an amphipathic lipid, there would be no motivation to use the method of *Vanlerberghe et al.* to prepare the microdispersion of *Nakamura.*

Appellants thank the examiner for withdrawing the rejection which gave rise to issue 4) page 12, first full paragraph of Examiner's Answer).

Appellants submit that in view of the deficiencies noted above, the decision of the primary examiner must be reversed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Norman F. Oblon
Attorney of Record
Registration No. 24,618

Richard L. Chinn, Ph.D.
Registration No. 34,305

Thomas W. Barnes III, Ph.D.
Registration Number 52,595

22850

Telephone: (703) 413-3000
Facsimile: (703) 413-2220